

**REMARKS**

I. In item 2 on page 2 of the Office Action, the Examiner raised a formal issue.

It is believed the above claims and instructions are in compliance with the rules.

II. In Item 3 on page 2 of the Office Action, claims 11-13, 18 and 19 were rejected under 35 U.S.C. §112, first paragraph, for an alleged want of enablement.

The rejection is traversed for the following reasons.

The formulation used in the working examples was a ready made product containing EGF intended for treating burns. The cream was obtained from an Algerian company, and manufactured in Cuba. The cream contained sulfadiazine acting as an antibiotic in the treatment of burns and as a preservative.

Thus, the sulfadiazine has effects unrelated to the claimed invention.

The instant application makes clear that EGF is the active agent of interest. Other ingredients are optional. The specification does not indicate that sulfadiazine is obligatory in the treatment of psoriasis. As known in the art, EGF has a specific cell surface receptor, and likely operates via a typical ligand/cognate receptor mechanism.

Turning now to some of the points raised by the Examiner, as to the first Forman factor, the instant specification thoroughly teaches a novel and inventive approach for treating psoriasis, and there is clearly a desperate need for same.

As to the second Forman factor, Applicant concurs.

Regarding the issue of predictability, as the sulfadiazine acts independently of the EGF for treating psoriasis, that is, the sulfadiazine serves an excipient function being a preservative, it is clear that the trial described in the instant specification speaks to the use of EGF on psoriasis, and thus that trial supports the patentability of the pending claims.

The previously filed Rule 132 Declaration summarized the state of the art prior to the filing of the instant application. However, it is clear the instant specification discloses the actual use of EGF for treating psoriasis. Thus, the conclusions of the Rule 132 Declaration are of no moment as to teachings of the instant invention.

As to Forman factor 6, one of skill in the art would recognize on reading the instant specification that the invention relates essentially to the use of EGF to treat psoriasis. The artisan would recognize that the presence of sulfadiazine in the cream of the working examples has no relevance to the intended effect of interest. Topical preparations are known to carry a number of ancillary ingredients, such as preservatives.

It is the current position of the inventor that the sulfadiazine present in the cream of the working examples has no impact on psoriasis. Thus, the working examples are probative on the instant inquiry of enablement.

Regarding Forman factor 8, applicant disagrees with the assessment of the Examiner in light of the explicit and thorough teachings of the instant specification on the use of EGF to treat psoriasis.

Additional activities pertinent to the issue are the recent allowance of claims in the corresponding application in the EPO containing claims directed to the use of EGF, and a second and larger clinical trial on the use of a cream containing 10 µg/g of EGF.

It is believed that the instant application and claims are enabled. In considering, for example, the Forman factors, and the rebuttal of the applicant to the points raised by the Examiner, it is clear that a prima facie case of non-enablement has not been made, and thus, the rejection can be removed.

III. In items 5 and 6 on pages 5 and 6 of the Office Action, claims 15 and 16 were rejected under 35 U.S.C. §103(a) over Nanney et al. in view of Phan et al.

The rejection is traversed for the following reason.

In item 6, the Examiner indicated that the rejection of claims 15 and 16 would be withdrawn if the patient is a human.

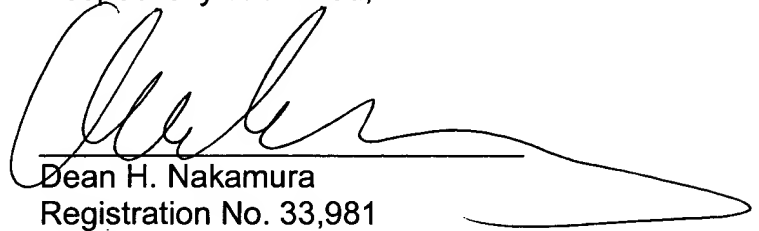
In light of the claim amendment, the rejection can be withdrawn.

**CONCLUSION**

Applicant submits that the pending claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections and early indication of allowance are requested respectfully. If any questions remain, the Examiner is urged to contact the undersigned at the local exchange noted below.

If any fees are found to be applicable, please charge any additional fees or make any credits to Deposit Account No. 07-1896.

Respectfully submitted,



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